

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

CATHY A. RUSSELL,

No. 4:20-CV-00405

Plaintiff,

(Judge Brann)

v.

ETHICON, INC. and
JOHNSON & JOHNSON,

Defendants.

MEMORANDUM OPINION

OCTOBER 9, 2020

I. BACKGROUND

This is a case of personal injury predicated on this Court’s diversity jurisdiction and brought under Pennsylvania law. Cathy A. Russell (“Plaintiff”) filed suit against Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) on March 18, 2015 as a member action in the Multidistrict Litigation (“MDL”) titled *In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation*.¹ Ethicon filed an initial motion for partial summary judgment in October 2018.² After proceeding through discovery in the MDL, the case was transferred to this Court in March 2020.³

¹ Master File No. 2:12-MD-02327. United States District Judge Joseph R. Goodwin of the Southern District of West Virginia presided over the Multidistrict Litigation.

² Doc. 27.

³ Doc. 56.

In May 2020, Ethicon sought leave to file a supplemental motion for summary judgment in order to raise a defense based on the applicable statute of limitations.⁴ After examination of the question and other courts' treatment of similar motions by Ethicon, I determined that consideration of that issue alongside the initial motion for partial summary judgment would be economical, and therefore granted Ethicon's motion.⁵ Ethicon filed a supplemental motion for summary judgment on June 24, 2020.⁶

Both summary judgment motions are now ripe for disposition; for the reasons that follow, Ethicon's motion for partial summary judgment is granted in part and denied in part, and Ethicon's supplemental motion for summary judgment is denied.

II. DISCUSSION

A. Standard of Review

I begin my analysis with the standard of review which undergirds summary judgment. “One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses, and we think it should be interpreted in a way that allows it to accomplish this purpose.”⁷

Summary judgment is appropriate where “the movant shows that there is no

⁴ Doc. 69.

⁵ Doc. 72.

⁶ Doc. 73.

⁷ *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986).

genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”⁸ “Facts that could alter the outcome are ‘material facts,’ and disputes are ‘genuine’ if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct.”⁹ “A defendant meets this standard when there is an absence of evidence that rationally supports the plaintiff’s case.”¹⁰ “A plaintiff, on the other hand, must point to admissible evidence that would be sufficient to show all elements of a *prima facie* case under applicable substantive law.”¹¹

“The inquiry involved in a ruling on a motion for summary judgment or for a directed verdict necessarily implicates the substantive evidentiary standard of proof that would apply at the trial on the merits.”¹² Thus, “if the defendant in a run-of-the-mill civil case moves for summary judgment or for a directed verdict based on the lack of proof of a material fact, the judge must ask himself not whether he thinks the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented.”¹³ “The mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which the jury

⁸ Fed. R. Civ. P. 56(a).

⁹ *Clark v. Modern Grp. Ltd.*, 9 F.3d 321, 326 (3d Cir. 1993) (Hutchinson, J.) (*citing Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) and *Celotex*, 477 U.S. at 322).

¹⁰ *Clark*, 9 F.3d at 326.

¹¹ *Id.*

¹² *Liberty Lobby, Inc.*, 477 U.S. at 252.

¹³ *Id.*

could reasonably find for the plaintiff.”¹⁴ “The judge’s inquiry, therefore, unavoidably asks . . . ‘whether there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed.’”¹⁵ The evidentiary record at trial, by rule, will typically never surpass that which was compiled during the course of discovery.

“A party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.”¹⁶ “Regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c), is satisfied.”¹⁷

Where the movant properly supports his motion, the nonmoving party, to avoid summary judgment, must answer by setting forth “genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.”¹⁸ For movants and nonmovants alike, the

¹⁴ *Id.*

¹⁵ *Id.* (quoting *Schuylkill & Dauphin Imp. Co. v. Munson*, 81 U.S. 442, 447 (1871)).

¹⁶ *Celotex*, 477 U.S. at 323 (internal quotations omitted).

¹⁷ *Id.*

¹⁸ *Liberty Lobby*, 477 U.S. at 250.

assertion “that a fact cannot be or is genuinely disputed” must be supported by:

(i) ”citing to particular parts of materials in the record” that go beyond “mere allegations”; (ii) ”showing that the materials cited do not establish the absence or presence of a genuine dispute”; or (iii) “showing . . . that an adverse party cannot produce admissible evidence to support the fact.”¹⁹

“When opposing summary judgment, the non-movant may not rest upon mere allegations, but rather must ‘identify those facts of record which would contradict the facts identified by the movant.’”²⁰ Moreover, “if a party fails to properly support an assertion of fact or fails to properly address another party’s assertion of fact as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion.”²¹ On a motion for summary judgment, “the court need consider only the cited materials, but it may consider other materials in the record.”²²

Finally, “at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.”²³ “There is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a

¹⁹ Fed. R. Civ. P. 56(c)(1).

²⁰ *Port Auth. of N.Y. and N.J. v. Affiliated FM Ins. Co.*, 311 F.3d 226, 233 (3d Cir. 2003) (Weis, J.).

²¹ Fed. R. Civ. P. 56(e)(2).

²² Fed. R. Civ. P. 56(c)(3).

²³ *Liberty Lobby*, 477 U.S. at 249.

verdict for that party.”²⁴ “If the evidence is merely colorable . . . or is not significantly probative, summary judgment may be granted.”²⁵

B. Undisputed Facts

With that standard outlining the Court’s framework for review, I now turn to the undisputed facts of this matter.

On August 20, 2004, Plaintiff attended a doctor’s appointment with Dr. Vatche A. Minassian. At that appointment, Plaintiff presented “with a five-year history of urinary incontinence.”²⁶ She related her symptoms to “the birth of her child after which she started having loss of urine with cough, sneeze, laughing, exercise, and walking.” On March 23, 2005, Dr. Minassian performed a tension-free vaginal tape (“TVT”) operation on Plaintiff in order to treat her stress urinary incontinence (“SUI”).²⁷ During examination on June 29, 2005, Dr. Minassian noted that a piece of the mesh was exposed at the mid-urethra and instructed Plaintiff to apply estrogen cream for two to three weeks.²⁸ Dr. Minassian further commented that if there was no resolution, a revision surgery would be necessary.²⁹ Dr. Minassian subsequently performed the first revision surgery on Plaintiff on July 26, 2005.

²⁴ *Id.*

²⁵ *Id.* at 249–50 (internal citations omitted).

²⁶ Doc. 75, Ex. 4 (RUSSELLC_GEMC_MDR00159).

²⁷ Doc. 75, Ex. 5 (RUSSELLC_PSR_00003).

²⁸ Doc. 75, Ex. 6 (RUSSELLC_GEMC_MDR00329-00331).

²⁹ *Id.*

Approximately two months after the first revision surgery, Plaintiff visited Dr. Minassian again. During that visit, Dr. Minassian discovered that the mesh had eroded again.³⁰ Plaintiff continued to experience stress urinary incontinence.³¹ Dr. Minassian scheduled and performed a second revision surgery on Plaintiff on October 17, 2005.³² Thereafter, Plaintiff's last visit with Dr. Minassian was in 2007. Plaintiff later filed suit on March 18, 2015 by filing the short form complaint in the multidistrict litigation.

C. Analysis

Before providing analysis of the parties' arguments, the Court engages in a summary of the claims remaining in this litigation. On October 16, 2018, Ethicon filed its initial motion for summary judgment.³³ At that time, Plaintiff had alleged a variety of claims and theories of recovery. In her opposition to the motion for summary judgment, filed on October 23, 2018, Plaintiff narrowed the scope of the litigation.³⁴ Plaintiff opposes summary judgment as to the following counts and claims: Count 1 (negligence, failure to warn); Count 3 (strict liability, failure to warn); Count 5 (strict liability, design defect); and Count 14 (gross negligence, failure to warn).³⁵ Plaintiff further stated that she would not attempt to proceed to

³⁰ Doc. 75, Ex. 9 (RUSSELLC_GEMC_MDR00502-00503).

³¹ *Id.*

³² Doc. 75, Ex. 10 (RUSSELLC_GEMC_MDR00521).

³³ Doc. 27.

³⁴ Doc. 29.

³⁵ *Id.*

trial with the following counts: 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, and 15.³⁶ Finally, Plaintiff noted that Ethicon did not move for summary judgment on her punitive damages claim, or her claims for negligence or gross negligence based on allegations of design defect (also alleged in Count 1).³⁷

1. The Statute of Limitations

The threshold question for this Court is whether Ethicon is entitled to summary judgment based on the statute of limitations. If the answer to that question is “yes,” then Plaintiff’s claims must be dismissed in their entirety. If the answer is “no,” the Court must consider whether each individual claim is susceptible to summary judgment.

Claims such as those brought by Plaintiff must generally be commenced within two years of “when an injury is inflicted.”³⁸ This rule is not, however, without exception. “[W]here the plaintiff’s injury or its cause was neither known nor reasonably ascertainable,” the statute of limitations is tolled by the discovery rule.³⁹ This rule tolls the statute of limitations where the Plaintiff is “unaware that [s]he has been injured and that [her] injury has been caused by another party’s conduct.”⁴⁰

³⁶ *Id.*

³⁷ *Id.*

³⁸ See 42 Pa. Cons. Stat. § 5524; *Wilson v. El-Daief*, 964 A.2d 354 (Pa. 2009).

³⁹ *Nicolaou v. Martin*, 195 A.3d 880, 892 (Pa. 2018).

⁴⁰ *Id.*

When the discovery rule is implicated, the “commencement of the limitations period is grounded on ‘inquiry notice’ that is tied to ‘actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another’s conduct, without the necessity of notice to the full extent of the injury, the fact of actual negligence, or precise cause.’”⁴¹ As such, the statute of limitations “begins to run when the plaintiff knew or, exercising reasonable diligence, should have known (1) he or she was injured and (2) that the injury was *caused by another.*”⁴²

As the United States Court of Appeals for the Third Circuit recently explained in *Adams v. Zimmer*, it is a “well-established general rule” in Pennsylvania that “the factual issues pertaining to Plaintiffs’ notice and diligence are for a jury to decide.”⁴³ “Where, however, reasonable minds would not differ in finding that [Plaintiff] knew or should have known on the exercise of reasonable diligence of [her] injury and its cause, … the discovery rule does not apply as a matter of law.”⁴⁴

The parties dispute whether the discovery rule tolled the statute of limitations such that Plaintiff’s complaint was timely filed. Ethicon contends that “the limitations period on Plaintiff’s claims began to run in October of 2005, when

⁴¹ *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011).

⁴² *Adams v. Zimmer US, Inc.*, 943 F.3d 159 (3d Cir. 2019) (emphasis added).

⁴³ *Id.* at 164 (quoting *Nicolaou*, 195 A.3d at 894).

⁴⁴ *Fine v. Checcio*, 870 A.2d 850, 858-59 (Pa. 2005).

she had symptoms of her claimed injuries, had the second of two procedures concerning her eroded mesh, and should reasonably have attributed her symptoms to her mesh.⁴⁵ Plaintiff predictably disagrees with that characterization, arguing that there are genuine issues of material fact as to “whether the statute of limitations was tolled until Plaintiff became aware not only of her injuries, but also that their injuries were caused by [Ethicon’s] product and its defects.”⁴⁶

At the outset, the Court rejects Plaintiff’s contention that she must have known about the product’s *defects* to trigger the statute of limitations. As described in the discussion of the case law above, that is not necessary. A plaintiff does not need to know that a product is defective to be subject to the statute of limitations. The fact that a plaintiff is not aware that she may have a cause of action is “irrelevant to the discovery rule analysis.”⁴⁷

It is undisputed that Plaintiff experienced pain long before she filed her complaint. She began seeing a doctor to address this in 2005. Therefore, the outstanding question in the discovery rule analysis is whether Plaintiff understood the potential cause of her injury, distinct from whether that cause was tortious. This Court finds that Plaintiff did not have actual knowledge of the cause of her injury. A “lay person is only charged with the knowledge communicated to him or

⁴⁵ Doc. 74 at 11.

⁴⁶ Doc. 76-1 at 6.

⁴⁷ *Burton-Lister v. Siegel, Sivitz and Lebed Assoc.*, 798 A.2d 231, 237 (Pa. Super. Ct. 2002).

her by the medical professionals who provided treatment and diagnosis.”⁴⁸ The record suggests that Plaintiff was told that the mesh was not the cause of her injury; instead, it appears that Plaintiff’s doctor, Dr. Minassian, believed that Plaintiff’s obesity and habitual smoking caused the mesh erosion itself, which in turn caused her pain. Relevant portions of Dr. Minassian’s deposition transcript are recreated below:

Q: Okay. Did you conduct a physical examination?

A: Yes.

Q: And what did you find?

A: I noted that the vaginal -- that the mesh had eroded back through the same spot in the vagina.

Q: And what was --

A: And the eroded segment was a little larger in one of the dimensions.

Q: Did you have any impression about why the mesh had eroded again?

A: I don’t list it in my note, but because of her history of obesity and smoking, my impression now, as it would have

⁴⁸ *Nicolaou v. Martin*, 195 A.3d 880, 893 (Pa. 2018).

been back then, would be that those were risk factors for either poor healing or failure for the first revision to be successful.

Q: And were those things that you explained during the consent process?

A: Yes.

Q: And is that why you asked her to stop smoking?

A: Yes.

Q: And lose some weight?

A: Yes.⁴⁹

Based on Dr. Minassian's testimony, the Court declines to hold that the discovery rule does not apply as a matter of law, because it believes that reasonable minds could differ on the question of whether Plaintiff should have known of the cause of injury. While Plaintiff was aware that she was in pain, "the mere experience of a physical condition does not trigger any obligation to actively seek out further information, including whether it is the result of another person's conduct."⁵⁰ Given what Plaintiff was told about *why* the mesh was exposed (her obesity and smoking habits), it is reasonable that she would not continuously consult with her physicians to determine whether or not the device was defective. The number of visits she did undertake is enough to at least create a jury question

⁴⁹ Doc. 76, Ex. B at 54:14-55:4.

⁵⁰ *In re Risperdal Litigation*, 223 A.3d 633, 644 (Pa. 2019).

as to her diligence. The Court cannot say that, as a matter of law, that the discovery rule does not apply. Instead, this Court agrees with the numerous Pennsylvania courts that have held that this question is “best determined by the collective judgment, wisdom, and experience of jurors.”⁵¹ Ethicon’s supplemental motion for summary judgment on the statute of limitations is therefore denied.

2. Russell’s Negligence and Gross Negligence Claims

Plaintiff raises negligence and gross negligence claims based on a failure to warn (Counts 1 and 14). To sustain a failure to warn claim under Pennsylvania law, Plaintiff must show: “that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries.”⁵²

Furthermore, it is “well settled that under Pennsylvania law, the learned intermediary doctrine requires the duty to run from the manufacturer of a prescription drug to the physician, and not to the patient or general public.” Under the learned intermediary doctrine,

[A] manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be dangerous. The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the

⁵¹ *Coleman v. Wyeth Pharms., Inc.*, 6 A.3d 502, 510 (Pa. Super. Ct. 2010).

⁵² *Bergstresser v. Bristol-Myers Squibb Co.*, 2013 WL 1760525 (M.D. Pa. Apr. 24, 2013).

patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.⁵³

This rule applies to both prescription drugs and medical devices.⁵⁴

Ethicon claims that summary judgment is appropriate because Plaintiff's doctor "was in fact aware of the risk of the injuries she allegedly suffered," and where "the treating physician knew of a particular risk of a device prior to implant, the absence of those risks in the product warning cannot be the proximate cause of the alleged injury."⁵⁵ Furthermore, Ethicon argues that Plaintiff failed to establish that "any alleged negligent warning was the proximate cause of her injuries."⁵⁶ Ethicon asserts that to establish proximate cause, Plaintiff would need to show that "her doctor would not have prescribed the drug had an adequate warning been given."⁵⁷

The record is unclear as to whether Dr. Minassian was aware of all the risks Plaintiff alleges. Ethicon points to the excerpt below for support:

Q: Based on your education, your training, your clinical experience and your review of the medical literature over the years, are there any complications that the plaintiff Ms. Russell, experienced here that you were not aware of prior to implanting the TVT.

⁵³ *Gurley v. Janssen Pharm., Inc.*, 113 A.3d 283, 292-93 (Pa. Super. Ct. 2015).

⁵⁴ *Soufflas v. Zimmer, Inc.*, 474 F.Supp.2d 737, 751 (E.D. Pa. 2007).

⁵⁵ *Id.* at 11.

⁵⁶ Doc. 28 at 10.

⁵⁷ *Id.*

A: No.⁵⁸

In response, Plaintiff directs the Court to a subsequent exchange during the deposition:

Q: Okay. Would – back in 2005, would dyspareunia have been something that, under your custom and practice, you would have mentioned to her in 2005?

A: Good question. You know, thinking back about the development of the TVT, TOT, I don't know if in 2005 dyspareunia was either a big thing or something that was a recognized potential complication after sling procedures. So I don't know the answer to that question.

Q: Doctor, if you had data in 2005 to suggest that dyspareunia was a factor in risk complications for TVT, would that have been something that would have informed your decision as to whether or not to go ahead with a TVT operation or not?

A: It would take – it would play a role in my discussion, or you know, the informed consent that we're taking from the patient as a potential risk or complication.⁵⁹

Q: Okay.

⁵⁸ Doc. 27, Ex. 3, 67:22-68:4.

⁵⁹ Doc. 27, Ex. 3, 72:21-73:25.

A: But in hindsight, I don't think it would have made me sway the patient one direction versus the other.

Accordingly, Ethicon's assertion that Plaintiff's physician was aware of the risk of the injuries she allegedly suffered is unclear. What is not in dispute, however, is the issue of proximate cause. Plaintiff has not submitted evidence to support the contention that there is a triable issue of fact about Dr. Minassian's awareness of Ethicon's instructions for use ("IFU").

To establish proximate causation in a failure to warn claim, Plaintiff must show that Dr. Minassian would have altered his behavior if Ethicon had provided a more accurate warning.⁶⁰ However, the record does not establish a genuine dispute as to this point. Dr. Minassian testified as follows:

Q: I wanted to ask you some questions. Are you familiar with something called the instructions for use, Doctor?

A: No.

Q: Well, there are certain instructions that come with the particular device. Have you read those instructions or not?

A: I don't recall.

Q: Okay. In any event, do you use those instructions for use when you're consenting the patient?

⁶⁰ *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. 1996).

A: No.⁶¹

Dr. Minassian's admissions that he does not recall reading the IFU and that he does not use the IFU when consenting patients are fatal to this particular claim. First, if the physician does not read the warnings provided, the failure to provide an additional warning cannot be the proximate cause of an injury, because even if said additional warning had been provided, the doctor, having failed to review the warning in the first place, would be unaware. Second, Plaintiff's attempt to salvage her claim by pointing to some equivocation in Dr. Minassian's answer is unavailing. Plaintiff argues that the mere fact that Dr. Minassian did not *remember* whether he had read the IFU creates a genuine dispute of material fact. It does not.

Dr. Minassian's "lack of memory, of course, does not preclude the possibility that [he] read these materials, but neither can it sustain [Plaintiff's] burden."⁶² Plaintiff "was not foreclosed from pointing to contrary evidence in the record that would suggest that [Dr. Minassian] did read and rely upon [Ethicon's] inadequate warning, but she has failed to do so."⁶³ Therefore, even if Ethicon's warning was inadequate, Plaintiff has not provided evidence that the warning was a

⁶¹ Doc. 27, Ex. 3, 67:10-21.

⁶² *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 277 (5th Cir. 2010) (applying Texas's learned intermediary doctrine and upholding the grant of summary judgment where doctor did not recall whether she had read the provided warnings). See also, e.g., *In re Wright Medical Technology Inc., Conserve Hip Implant Products Liability Litig.*, 127 F.Supp.3d 1306, 1360-61 (N.D. Ga. 2015); *Motus v. Pfizer Inc.*, 196 F.Supp.2d 984, 996 (C.D. Cal. 2001).

⁶³ *Fulgenzi v. PLIVA, Inc.*, 140 F.Supp.3d 637, 650 (N.D. Oh. 2015).

proximate cause of her injuries. Accordingly, the Court grants summary judgment as to the failure to warn claims.

3. Russell's Strict Liability Claims

Plaintiff has alleged strict liability claims for both failure to warn (Count 3) and design defect (Count 5).⁶⁴ Ethicon argues that Plaintiff's strict liability claims are barred as a matter of law because Pennsylvania does not recognize such claims for medical devices, pursuant to Restatement (Second) of Torts § 402A, comment k. Federal district courts in Pennsylvania differ on this question.⁶⁵ As I noted in another opinion on this issue, I find the Honorable Gerald J. Pappert's reasoning in a recent decision, *Ebert v. C.R. Bard, Inc.*, No. CV 12-01253, 2020 WL 2332060, at *9-*10 (E.D. Pa. May 11, 2020), persuasive, and again adopt it here.

In short, the 2006 Pennsylvania Superior Court decision *Creazzo v. Medtronic, Inc.*,⁶⁶ which district courts often rely on to predict a categorical ban, is “supported by scant reasoning and in the fourteen years since *Creazzo*, the Pennsylvania Supreme Court has not relied on it.”⁶⁷ This makes *Creazzo*, in this Court’s eyes, not particularly persuasive. Second, two 2014 Pennsylvania Supreme

⁶⁴ First, the Court notes that Count 3 is dismissed for the same reasons as Plaintiff's negligence-based failure to warn claims; Plaintiff has failed to establish a triable issue as to causation based on the warning. The Court now considers whether Plaintiff's design defect claim survives summary judgment.

⁶⁵ The Honorable Jeffrey L. Schmehl discusses the two different stances in a somewhat recent decision, *Wilson v. Synthes USA Prod., LLC*, 116 F. Supp. 3d 463, 466 (E.D. Pa. 2015).

⁶⁶ 903 A.2d 24 (Pa. Super. Ct. 2006).

⁶⁷ *Ebert v. C.R. Bard, Inc.*, No. CV 12-01253, 2020 WL 2332060, at *10 (E.D. Pa. May 11, 2020).

Court decisions,⁶⁸ “taken together, undermine *Creazzo*’s persuasive force and suggest that the Pennsylvania Supreme Court would not apply comment k [of the Restatement (Second) of Torts] to categorically exempt all prescription medical devices from strict liability claims.”⁶⁹

Based on the above, this Court “predicts that the Pennsylvania Supreme Court would not categorically [bar strict liability claims against] all prescription medical device manufacturers. Rather, the Court predicts that Pennsylvania’s highest court would instead analyze [strict liability’s] applicability to prescription medical devices on a case-by-case basis, determined largely by each case’s developed factual record and the individual characteristics of the medical device at issue.”⁷⁰

Here, based on the evidence before the Court, I cannot determine that the mesh used to treat Plaintiff’s SUI is an “unavoidably unsafe product” that is shielded from strict liability claims under Pennsylvania law. Ethicon merely invokes comment k without providing any argument or evidence as to why its product is immune from liability. Without more, this Court cannot conclude that “in the present state of human knowledge,” Ethicon’s mesh was “quite incapable of being made safe for [its] intended and ordinary use.”⁷¹ Absent evidence to support

⁶⁸ See *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 396 (Pa. 2014); *Lance v. Wyeth*, 85 A.3d 434, 454 (Pa. 2014).

⁶⁹ *Ebert*, 2020 WL 2332060, at *10.

⁷⁰ *Id.*

⁷¹ Restatement (Second) of Torts, § 402A, comment k.

the assertion that its product is unavoidably unsafe, Ethicon's motion for summary judgment on Count 5 must be denied, as it raises no other grounds to dismiss Plaintiff's strict liability design defect claim.

III. CONCLUSION

Ethicon's motion for summary judgment is granted as to Counts 1 (only with regard to Plaintiff's failure to warn theory), 3, and 14. The motion is denied as to Count 5. Because Counts 17 (punitive damages) and 18 (discovery rule and tolling) are remedies and doctrines still relevant to the litigation, the Court does not address those separately, but notes that: (1) an independent cause of action for punitive damages is not recognized for product liability claims in Pennsylvania;⁷² and (2) likewise, the discovery rule is a doctrine which impacts the statute of limitations, not a separate cause of action.⁷³

An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann
Matthew W. Brann
United States District Judge

⁷² *Hoover v. Sunbeam Products, Inc.*, 2010 11678339 at *5 (M.D. Pa. July 27, 2010) (collecting cases).

⁷³ *Wilson v. El-Daief*, 964 A.2d 354, 363 (Pa. 2009).